# Mylan Brings Critical Access to the Multiple Sclerosis Community by Launching a More Affordable Treatment Option Through a First Generic to Tecfidera®

HERTFORDSHIRE, England and PITTSBURGH, Aug. 19, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced the launch of the first FDA-approved therapeutically equivalent, substitutable generic of Biogen's Tecfidera® capsules. Dimethyl fumarate delayed release capsules 120 mg and 240 mg are indicated for the treatment of relapsing forms of multiple sclerosis (MS), and are the first generic of any MS treatment in an oral solid dosage form available to patients in the U.S.

Mylan CEO Heather Bresch said: "The launch of the first generic Tecfidera is yet another prime example of Mylan's fundamental commitment to bringing more access to patients worldwide, in this particular case through our important continued support of the MS community, while helping to provide immediate and substantial savings for the U.S. healthcare system. It also represents another significant achievement for the many Mylan scientific, regulatory and legal colleagues who continue to work tirelessly in doing their part to bring important access to medicines as quickly as possible."

Mylan President Rajiv Malik said: "Our commitment to the MS community stems all the way back to our initial investment in 2009 to bring a first generic Copaxone to market, which we achieved in 2017. Today's launch represents yet another example of that commitment, by bringing access to the first generic of Tecfidera. While we are pleased with our accomplishments to date, we remain equally excited to expand our offerings by advancing work on a co-developed follow-on product for a once-monthly glatiramer acetate injection. I too would like to thank all of my colleagues for their passion and support in fulfilling our company's mission to expand access to high quality medicines."

The FDA approval follows Mylan's win in the U.S. District Court for the Northern District of West Virginia that invalidated Biogen's Tecfidera® patent, U.S. Patent No. 8,399,514. Biogen is appealing that decision.

Biogen's total IQVIA sales in the U.S. for the 12 months ending June 30, 2020, were approximately $3.79 billion for Tecfidera.

**About Mylan**

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

**Forward-Looking Statement**

This press release includes statements that constitute "forward-looking statements," including with regard to the approval and launch of the first generic to Tecfidera; that the launch is yet another prime example of Mylan's fundamental commitment to bringing more access to patients worldwide, in this particular case through our important continued support of the MS community, while helping to provide immediate and substantial savings for the U.S. healthcare system; that while we are pleased with our accomplishments to date, we remain equally excited to expand our offerings by advancing work on a co-developed follow-on product for a once-monthly glatiramer acetate injection; the outcome of litigation; that the FDA approval follows Mylan's win in the U.S. District Court for the Northern District of West Virginia that invalidated Biogen's Tecfidera® patent, U.S. Patent No. 8,399,514; and that Biogen is appealing that decision. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to the completion of the proposed combination of Mylan and Upjohn Inc., Pfizer Inc.'s off-patent branded and generic established medicines business, (the "Combination") on the anticipated timeline or at all, and the achievement of the anticipated benefits of the Combination; the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve

intellectual property rights; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

SOURCE Mylan N.V.

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